

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0721437	(X3) Date Survey Completed 09/17/2025
Name of Provider or Supplier Summit Medical Group Pa	Street Address, City, State 150 Park Ave, Florham Park, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control Records (QCR) and interview with the Laboratory Managers (LM), the laboratory failed to document all Quality Control (QC) information for Urinalysis tests performed on the Aution Eleven AE-4022 analyzer from 7/20/23 to 9/17/25 . The finding includes: 1. The laboratory did not document the lot numbers and expiration dates of QC material used on the Aution Eleven Daily QC reports. 2. The LM confirmed on 9/17/25 at 2:30 pm, the laboratory did not document all QC information.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of analyzer Quality Control Records (QC), review of the Manufacturer QC Assayed Value Sheet (MQCAVS) and interview with the Laboratory Managers (LM), the laboratory failed to follow the MQCAVS for routine</p>

chemistry testing performed on the Roach Cobas Integra from June 2025 to 9/17/25. The findings include: 1. The MQCAVS for level 1 did not match the QC records as follows: a) The MQCAVS had Creatinine (CR) listed as .94-1.01 mg/dL the QC records had .79-1.11 mg/dL . b) The MQCAVS had Total Bilirubin (TBIL) listed as .371-.687 mg/dL the QC records had .371-.69 mg/dL 2. The MQCAVS for level 3 did not match the QC records as follows: a) The MQCAVS had CR listed as 5.25-6.45 mg/dL the QC records had 5.96-7.16 mg/dL 3. The LM confirmed on 9/17/25 at 11:40 am, the laboratory failed to follow the MQCAVS .

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on surveyor observation of the Quality Control (QC) reagents and interview with the Laboratory Managers (LM), the laboratory failed to document appropriate expiration dates on the Bio-Rad Liquichek Cardiac Markers Plus Control LT QC reagents in use on the Roach Cobas e411 analyzer from 9/16/25 to 9/17/2025. The findings include: 1. The Manufacturers Package Insert (MPI) stated "open vial stability is 4 days after opening and reconstituting." 2. The laboratory recorded an open and reconstitution date of 9/16/25 on the Bio-Rad Liquichek Cardiac Markers Plus Control LT . 3. Bio-Rad Liquichek Cardiac Markers Plus Control LT were then stable until 9/20/25, but the laboratory had a stability date of 9/26/25 recorded on the QC. 4. The LM confirmed on 9/17/25 at 11:10 am, the laboratory failed to document appropriate expiration dates on opened QC reagents.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on surveyor observation of staining reagents and interview with the Laboratory Managers (LM) the laboratory used expired staining reagents for Hematology tests from 9/12/25 to 9/17/25. The finding includes: 1. The Hema-Tek Stain Pak lot #146520 in use was observed to be expired on 9/12/25. 2. Approximately 27 tests were performed and reported with the expired staining reagents. 3. The LM confirmed on 9/17/25 at 1:35 pm, the laboratory used expired staining reagents.